DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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December 22, 2014

BECKMAN COULTER, INC.
RYAN SEVERSON
SENIOR REGULATORY AFFAIRS ANALYST
1000 LAKE HAZELTINE DR.
CHASKA MN 55318-1084

Re: K142373
Trade/Device Name: Access 25(OH) Vitamin D Total for use on the Access 2 Immunoassay System,
Access 25(OH) Vitamin D Total Calibrators for use on the Access 2 Immunoassay System
Regulation Number: 21 CFR 862.1825
Regulation Name: Vitamin D test system
Regulatory Class: II
Product Code: MRG, JIT
Dated: November 17, 2014
Received: November 18, 2014

Dear Mr. Ryan Severson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the

electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Katherine Serrano -S

For: Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142373

Device Name
Access 25(OH) Vitamin D Total for use on the Access 2 Immunoassay System.
Access 25(OH) Vitamin D Total Calibrators for use on the Access 2 Immunoassay System.

Indications for Use *(Describe)*
The Access 25(OH) Vitamin D Total assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of total 25-hydroxyvitamin D [25(OH) vitamin D] levels in human serum and plasma using the Access 2 Immunoassay Systems. Results are to be used as an aid in the assessment of vitamin D sufficiency.

The Access 25(OH) Vitamin D Total Calibrators are intended to calibrate the Access 25(OH) Vitamin D Total assay for the quantitative determination of total 25-hydroxyvitamin D [25(OH) vitamin D] levels in human serum and plasma using the Access 2 Immunoassay Systems.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Section 3.2: 510(k) Summary

510(k) Summary

Prepared August 22, 2014

This summary of 510(k) safety and effectiveness is being submitted in accordance with the requirements of 21 CFR 807.92.

The Assigned 510(k) Number is: _____

Submitted By:

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Device Name

Proprietary/Trade Name:	Access 25(OH) Vitamin D Total for use on the Access 2 Immunoassay System.
Common Name:	25(OH) Vitamin D
Classification Name:	Vitamin D Test System
Classification Regulation:	21 CFR 862.1825
Product Code:	MRG

Proprietary/Trade Name:	Access 25(OH) Vitamin D Total Calibrators for use on the Access 2 Immunoassay System.
Common Name:	25(OH) Vitamin D Calibrators
Classification Name:	Calibrator, Secondary
Classification Regulation:	21 CFR 862.1150
Product Code:	JIT

Predicate Device

DiaSorin LIAISON 25 OH Vitamin D Total Assay (K112725).
DiaSorin LIAISON 25 OH Vitamin D Total Calibrators (K112725)
Manufactured by Diasorin, Inc.

Device Description

The Access 25(OH) Vitamin D Total for use on the Access 2 Immunoassay System, Access 25(OH) Vitamin D Total Calibrators for use on the Access 2 Immunoassay System, and the Access 2 Immunoassay analyzer comprise the Access Immunoassay System for the quantitative determination of total 25-hydroxyvitamin D[25(OH) vitamin D] levels in human serum and plasma.

The Access 25(OH) Vitamin D Total assay is a two-step sequential competitive binding immunoenzymatic assay. In the initial incubation, sample is added to a reaction vessel with a vitamin D binding protein (DBP) releasing agent and paramagnetic particles coated with sheep monoclonal anti-25(OH) vitamin D antibody. 25(OH) vitamin D is released from DBP and binds to the immobilized monoclonal anti-25(OH) vitamin D on the solid phase. Subsequently, a 25(OH) vitamin D analogue-alkaline phosphatase conjugate is added which competes for binding to the immobilized monoclonal anti-25(OH) vitamin D. After a second incubation, materials bound to the solid phase are held in a magnetic field while unbound materials are washed away. Then, the chemiluminescent substrate Lumi-Phos 530 is added to the vessel and light generated by the reaction is measured with a luminometer. The light production is inversely proportional to the concentration of 25(OH) vitamin D in the sample. The amount of analyte in the sample is determined from a stored, multi-point calibration curve.

Intended Use

The Access 25(OH) Vitamin D Total assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of total 25-hydroxyvitamin D [25(OH) vitamin D] levels in human serum and plasma using the Access 2 Immunoassay Systems. Results are to be used as an aid in the assessment of vitamin D sufficiency.

The Access 25(OH) Vitamin D Total Calibrators are intended to calibrate the Access 25(OH) Vitamin D Total assay for the quantitative determination of total 25-hydroxyvitamin D [25(OH) vitamin D] levels in human serum and plasma using the Access 2 Immunoassay Systems.

Comparison of Technological Characteristics

Parameter	Diasorin 25 OH Vitamin D Total.	Access 25(OH) Vitamin D Total
Intended Use	The LIAISON® 25 OH Vitamin D TOTAL Assay uses chemiluminescent immunoassay (CLIA) technology for the quantitative determination of 25-hydroxyvitamin D and other hydroxylated vitamin D metabolites in human serum, to be used in the assessment of vitamin D sufficiency using the LIAISON® Analyzer family. Assay results should be used in conjunction with other clinical or laboratory data to assist the clinician in making individual patient management decisions in an adult population.	The Access 25(OH) Vitamin D Total assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of total 25-hydroxyvitamin D [25(OH) vitamin D] levels in human serum and plasma using the Access 2 Immunoassay System. Results are to be used as an aid in the assessment of vitamin D sufficiency.
Analyte Measurand	25(OH) Vitamin D	25(OH) Vitamin D
Standardization	Standard prep: UV ε	NIST-Ghent ID-LC-MS/MS
Technology	Competitive Immunoassay	Competitive Immunoassay
Format	Chemiluminescent	Chemiluminescent
Method	Automated	Automated
Calibration	Utilizes a stored calibration curve.	Utilizes a stored calibration curve
Sample Type	Serum	Serum/Li Hep Plasma
Measuring Range	4-150 ng/mL	7.0-120 ng/mL (17.5 to 300 nmol/L)

Summary of Studies

Method Comparison: A comparison of 279 samples, ranging from 7.48 ng/mL to 118.83 ng/mL was run on both the Access 25(OH) Vitamin D Total assay and the predicate DiaSorin LIAISON 25 OH Vitamin D Total. The new method was correlated with the predicate using Passing Bablok analysis and the observed correlation coefficient was 0.89. A secondary comparison of 110 samples, ranging from 8.0 ng/mL to 98.6 ng/mL (20 nmol/L to 246.5 nmol/L), was completed on the Access 25(OH) Vitamin D Total assay and the 25(OH) Vitamin D ID LC-MS/MS Reference Measurement Procedure (RMP) from Ghent University (Ghent RMP). Analysis was completed using Passing Bablock, and the observed slope and correlation coefficient were 1.01 and 0.95, respectively.

Imprecision: This assay exhibits total imprecision ≤ 10.0% at concentrations greater than 15.0 ng/mL and total Standard Deviation (SD) ≤ 1.5 ng/mL at concentrations ≤ 15.0 ng/mL. Representative studies demonstrated that the within-run % CV ranged from 1.4% to 2.7% , the between-run % CV ranged from 5.2% to 7.2%, and the total % CV ranged from 5.5% to 7.5% for 25(OH) Vitamin D (25OHD) concentrations > 15.0 ng/mL. The within-run SD was 0.5 ng/mL across three test conditions, the between-run SD ranged from 0.9 to 1.0 ng/mL, and the total SD ranged from 1.0 to 1.1 ng/mL for 25OHD concentrations ≤ 15.0 ng/mL.

Linearity: The results indicate that the Access 25(OH) Vitamin D Total assay demonstrates linearity across the measuring range from 7.0 to 120 ng/mL.

Limit of Blank (LoB): For the purposes of the assay Instructions for Use, the LOB will be 1.50 ng/mL. Representative data showed that the highest measurement result observed with no analyte present was determined to be 0.55 ng/mL.

Limit of Detection (LoD): For the purposes of the assay Instructions for Use, the LOD will be 2.00 ng/mL. Representative data showed that the lowest concentration of analyte in a sample that can be detected with a stated probability (95%) was determined to be 1.0 ng/mL.

Limit of Quantitation (LoQ): For the purposes of the assay Instructions for Use, the LOQ will be 7.0 ng/mL. Representative data showed that the lowest concentration in a sample that can be quantitatively determined with a % CV of 20% was determined to be 3.0 ng/mL.

Analytical Specificity: Normal human blood constituents and commonly encountered medications do not cause interference in the Access 25 (OH) Vitamin D Total Assay. Hemoglobin does not cause interference in the Access 25 (OH) Vitamin D Total Assay up to 0.5 g/L.

Cross Reactivity: Cross-reactants do not cause interference in the Access 25 (OH) Vitamin D Assay, with the exception of Paracalcitol. Cross reactivity studies indicate that falsely elevated results may occur in patients being treated with Paricalcitol.

Population Observation Group: This study measured 25(OH) vitamin D in serum samples from 367 apparently healthy male and female adults 21 years of age and older. The 95% Reference interval of 25(OH) vitamin D concentrations found in this population range from 11.9 - 43.6 ng/mL.

Substantial Equivalence Comparison

Beckman Coulter believes the Access 25(OH) Vitamin D Total for use on the Access 2 Immunoassay System is substantially equivalent to the DiaSorin LIAISON 25 OH Vitamin D Total Assay (K112725). Tables 2 and 3 provide a summary of the pertinent similarities and differences between these two devices:

Table 2: Substantial Equivalence Comparison - Similarities		
Characteristic	***DiaSorin LIAISON 25 OH Vitamin D Total Assay (predicate, Calibrators Included)***	***Access 25(OH) Vitamin D Total for Use on the Access 2 Immunoassay System Reagent and Access 25(OH) Vitamin D Total Calibrators for Use on the Access 2 Immunoassay System.***
Reagent		
510(k) Number(s)	k112725	
Intended Use	The LIAISON® 25 OH Vitamin D TOTAL Assay uses chemiluminescent immunoassay (CLIA) technology for the quantitative determination of 25-hydroxyvitamin D and other hydroxylated vitamin D metabolites in human serum, to be used in the assessment of vitamin D sufficiency using the LIAISON® Analyzer family. Assay results should be used in conjunction with other clinical or laboratory data to assist the clinician in making individual patient management decisions in an adult population.	The Access 25(OH) Vitamin D Total assay is a paramagnetic particle, chemiluminescent immunoassay for the quantitative determination of total 25-hydroxyvitamin D [25(OH) vitamin D] levels in human serum and plasma using the Access 2 Immunoassay Systems. Results are to be used as an aid in the assessment of vitamin D sufficiency. The Access 25(OH) Vitamin D Total Calibrators are intended to calibrate the Access 25(OH) Vitamin D Total assay for the quantitative determination of total 25-hydroxyvitamin D [25(OH)D] levels in human serum and plasma using the Access 2 Immunoassay Systems.
Format	Chemiluminescent immunoassay	Same
Method	Automated	Same

Table 2: Substantial Equivalence Comparison - Similarities		
Characteristic	***DiaSorin LIAISON 25 OH Vitamin D Total Assay (predicate, Calibrators Included)***	***Access 25(OH) Vitamin D Total for Use on the Access 2 Immunoassay System Reagent and Access 25(OH) Vitamin D Total Calibrators for Use on the Access 2 Immunoassay System.***
Product Type	Reagent	Same
Assay Components	Calibrators	Same
	Reagent Pack	Same
Reportable units	ng/mL	ng/mL (nmol/L)
Assay type	Competition (direct); piggyback competition	2 Step Piggyback Competition assay
Calibrators		
510(k) Number(s)	k112725	
Material	Human Serum.	Same
Method	Automated	Same
Calibration	Utilizes a stored calibration curve	Same

The intended use, assay principal, test system, reagent pack configuration, assay method, assay type, and assay components of the subject device are equivalent to those of the predicate device.

Table 3: Substantial Equivalence Comparison - Differences		
Characteristic	***DiaSorin LIAISON 25 OH Vitamin D Total Assay (predicate, Calibrators Included)***	***Access 25(OH) Vitamin D Total for Use on the Access 2 Immunoassay System Reagent and Access 25(OH) Vitamin D Total Calibrators for Use on the Access 2 Immunoassay System.***
Reagent		
Sample Type	Serum	Serum/Li Hep Plasma
Immunoassay instrument	DiaSorin LIAISON	Access 2 Immunoassay System
Capture Antibody	Polyclonal Goat Aby (anti 25 OH Vit D)	Sheep monoclonal anti-25(OH) vitamin D
Sample Volume (µL)	250 for first run (25 for additional runs)	30
Analytical Measuring Range (ng/mL)	4-150	7.0 -120
Standardization	Standard prep: UV ε	NIST-Ghent ID-LC-MS/MS
Calibrators		
Calibrator Levels	2	6
Calibrator Materials	25-OH-D Horse serum, phosphate, surfactants, NaN3	Human Serum with 25(OH) vitamin D
Calibrator Number	2 cal levels (Low, high)	6 levels, zero and approximately 7, 18, 35, 74 and 167 ng/mL. (0, 18, 45, 88, 185 and 418 nmol/L))

Conclusion

The information provided in the sections cited above demonstrates that the proposed new device, the Access 25(OH) Vitamin D Total assay has the same intended use as the predicate device. In addition, verification and validation testing, the clinical and analytical data, and other scientific information provided in this submission demonstrate that the Access 25(OH) Vitamin D Total assay on the Access 2 Immunoassay System is substantially equivalent to the predicate device. This information establishes the substantial equivalence of Beckman Coulter's product to the predicate device.